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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,446	01/18/2000	HUGH W. PRICE	7841-89	5954

1059 7590 01/24/2005

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EXAMINER	
HINES, JANA A	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 01/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/402,446	PRICE ET AL.15	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23,25,26,31-39,57,59,60 and 64-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *23, 25-26, 31-39, 57, 59-60, 64-73* is/are allowed.

6)☒ Claim(s) *74-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed November 22, 2004 has been entered. Claims 23,25, 38, 57,, 59, 64, 71-72 have been amended. Claims 1-22, 24, 27-30, 40-56, 58 and 61-63 have been canceled. Therefore, claims 23, 25-26, 31-39, 57, 59-60, 64-80 are under consideration in this Office Action.

Withdrawal of Rejections

2. The following objections and rejections have been withdrawn in view of applicants' amendments and arguments:

a) the written description rejection of claims 23-29, 31-39 and 57-73 under 35 U.S.C. 112, first paragraph;
b) the scope of enablement rejection of claims 23-29, 31-39 and 57-73 under 35 U.S.C. 112, first paragraph; and
c) the rejection of claim 71 under 35 U.S.C. 112, second paragraph.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 74 and 78-80 are rejected under 35 U.S.C. 102(b) as being anticipated by Friesen (CA 1,201,063).

The claims are drawn to an aqueous immune globulin preparation for parenteral administration comprising an anti- Rh_oD immune globulin and at least one non-ionic surface active agent. The dependant claims are drawn to purity levels, monomeric content and being polyclonal.

Friesen teaches manufacturing of human plasma fractions containing immune globulin (IgG) wherein such fractions may be obtained in concentrated aqueous solution and are useful for intravenous injection (page 1 lines 1-5). It is noted that parenteral administration is defined as the introduction of substances into an organism by intravenous, subcutaneous, intramuscular or intramedullary injection. Thus Friesen teach immune globulin preparations for parenteral administration. The dilute solution containing the IgG is treated with a mixture of sodium chloride and glycine and the dilute solution thus obtained is subject to ultrafiltration to provide a concentrated solution containing IgG. The concentration of the glycine is 0.1M and the sodium chloride is 0.15M. (page 3 lines 23-27). The solution may be freeze-dried to provide a solid composition. The process is suitable for preparing Rh immune globulin for the prevention of Rh isoimmunization by passive administration of anti-D (page 1 lines 18-21). It is noted that the instant specification at page 15 teaches that Rh antibodies include anti-D (also known as anti- Rh_o or anti-Rh_oD). The purity, anticomplementary activity, safety and other test results were determined according to established procedures before the product (WINRHO) was used in clinical trials (page 4 lines 24-30). Thus the purity and recovery depends upon the ionic strength and pH of the eluting buffer wherein highly pure substances can be expected (page 9 lines 24-30). The

WinRho product is sold as a polyclonal anti-Rh_oD immune globulin. The authors teach a composition comprising Rh immune globulin (pages 4-5 lines 30- 21), just as instantly claimed. The concentrated pure immune globulin solution was stabilized by the addition of mannitol (page 9 lines 30-33). It is noted that specification defines non-ionic surface active agents as agents that are partial esters of common fatty acids, see page 18 of the instant specification. Fatty acid esters of polyhydroxyl compounds such as sorbitol and mannitol are compounds that are partially esterified with fatty acids that have surface active properties. Thus, mannitol meets the limitation of being a non-ionic surface active agent.

Therefore, Friesen teaches an aqueous immune globulin preparation for parenteral administration comprising a highly pure polyclonal anti- Rh_oD immune globulin and at least one non-ionic surface active agent.

5. Claims 74-76 and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by DeBurgh Bradley et al., (CA 1,303,533)

The claims are drawn to an aqueous immune globulin preparation for parenteral administration comprising an anti- Rh_oD immune globulin and at least one non-ionic surface active agent. The dependant claims are drawn to the non-ionic surface active agent, and the immune globulin being polyclonal.

de Burgh Bradley et al., herein referred to as Bradley et al., teach the use of human monoclonal anti-Rh (D) to prevent hemolytic disease in infants. It is noted that the instant specification at page 15 teaches that Rh antibodies include anti-D (also

known as anti- Rh_o or anti-Rh_oD). The antibodies can be used for passive immunization of a mother after birth (page 13 lines 17-22). It is noted that parenteral administration is defined as the introduction of substances into an organism by intravenous, subcutaneous, intramuscular or intramedullary injection. Thus Bradley et al., inherently teach immune globulin preparations for parenteral administration. An aqueous solution of monoclonal anti-Rh(D) immunoglobulin can be diluted with surfactants or suspending agents such as TWEEN 80™ (page 12 lines 20-33). Quantitation of anti-Rd(d) activity teaches diluting the immune globulin preparation with non-ionic surfactant TWEEN 20 ™. It is noted that non-ionic surface active agents are TWEEN type agents such as TWEEN 20 and 80 ™ are polyoxyethylene (20) sorbitan monolaurate and polyoxyethylene (20) sorbitan monooleate respectively, see page 19 of the instant specification that describes such agents as being polyoxyethylene sorbitan ester of a fatty acid. Thus, Bradley et al., teach non-ionic surface active agents which are both sorbitan esters of a fatty acid, and polyoxyethylene sorbitan esters of a fatty acid. Table V teaches the use of conventional polyclonal anti-Rh(D) serum (page 21 lines 18-21 and Table VI).

Therefore Bradley et al., teach an aqueous immune globulin preparation for parenteral administration comprising a monoclonal or polyclonal anti- Rh_oD immune globulin and at least one non-ionic surface active agent which are both sorbitan esters of a fatty acid, and polyoxyethylene sorbitan esters of a fatty acid, just as instantly claimed.

Allowable Subject Matter

6. Claims 23, 25-26, 31-39, 57, 59-60, 64-73 are allowed.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
January 11, 2005

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